June 22, 2005

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TARO

Taro Pharmaceuticals U.S.A., Inc.

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852.

CITIZEN PETITION

The undersigned submits this petition under section 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act and 21CFR Parts 314.55(d)(2) and 10.30 of the Food and Drug Administration's regulations to request the Commissioner of Food and Drugs to make a determination of ANDA suitability for Lidocaine Hydrochloride Injection USP, 2%, based on the discontinued reference-listed drug, Xylocaine® (Lidocaine Hydrochloride Injection, USP) 2% of AstraZeneca (NDA 06-488) [see exhibit 1].

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration for a change to a listed drug to allow the undersigned to submit an Abbreviated New Drug Application for Lidocaine Hydrochloride Injection USP, 2%. The reference-listed drug, Xylocaine® (Lidocaine Hydrochloride Injection, USP) 2% manufactured by AstraZeneca under NDA 06-488 has been discontinued.

B. Statement of Grounds

The Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) had listed under this same NDA a 2% strength of Xylocaine® (Lidocaine Hydrochloride Injection, USP) as reference-listed drug through September 2001 (21st edition), at which time the status of the 2% strength was changed to "discontinued" [see exhibit 2].

It is our belief that Xylocaine® (Lidocaine Hydrochloride Injection, USP) 2%, under NDA 06-488, was not discontinued due to safety reasons as there are currently twelve (non reference-listed) active products of 2% Lidocaine Hydrochloride Injection still listed in the Orange Book, including a non reference-listed Xylocaine (Lidocaine Hydrochloride Injection, USP) 2% manufactured by AstraZeneca under NDA 16-801 [see exhibit 3].

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The proposed Lidocaine HCl Injection USP, 2% will be the same as the reference-listed product, Xylocaine® (Lidocaine Hydrochloride Injection, USP) 1% of AstraZeneca in respect of:

- Active ingredient: Lidocaine Hydrochloride
- Indications
- Dosing regimen

A copy of the current labeling for Xylocaine® (Lidocaine Hydrochloride Injection, USP) 1% of AstraZeneca is included along with the proposed labeling for Taro's Lidocaine Hydrochloride Injection USP, 2% with highlighting of the changes is provided [see exhibit 4].

C. Environmental Impact

The undersigned hereby requests a categorical exclusion under 21CFR 25.24(c)(1). The proposed drug product will not be administered at higher dosage levels, for longer duration, or for different indications than for the reference-listed product.

D. Economic Impact

This information will be submitted on request of the Commissioner.

E. Advantages

The proposed Lidocaine Hydrochloride Injection USP, 2% will provide healthcare providers a greater flexibility in prescribing the drug.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

6/22/05

Kalpana Rao
Vice President, Regulatory Affairs (Global)